

109529522

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
8 April 2004 (08.04.2004)

PCT

(10) International Publication Number
WO 2004/028472 A3(51) International Patent Classification⁷: A61K 38/21,
38/00(21) International Application Number:
PCT/US2003/030532(22) International Filing Date:
26 September 2003 (26.09.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/414,307 27 September 2002 (27.09.2002) US(71) Applicant (for all designated States except US): BIOGEN
IDEC MA INC. [US/US]; 14 Cambridge Center, Cam-
bridge, Massachusetts 02142 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): SANDROCK, Alfred
[US/US]; 316 Hartman Road, Newton, MA 02459 (US).(74) Agent: CLAUSS, Isabelle, M.; Patent Group, Foley Hoag
LLP, 155 Seaport Boulevard, Boston, MA 02210 (US).(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE,
SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ,
VC, VN, YU, ZA, ZM, ZW.(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ,
TM), European patent (AT, BE, BG, CH, CY, CZ, DE,
DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL,
PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG,
CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

(88) Date of publication of the international search report:
19 January 2006For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.(54) Title: THERAPIES FOR CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY USING INTER-
FERON- β (57) Abstract: The present invention provides methods for the treatment, and pharmaceuticals for the use in the treatment, of
mammalian subjects having, or at risk of developing, chronic demyelinating neuropathies, e.g., CIDP. The methods involve the
administration of IFN- β therapeutics.

WO 2004/028472 A3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/30532

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : A61K 38/21; 38/00 US CL : 424/85.6; 514/12 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 424/85.6; 514/12 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	HADDEN.R.D.M. Randomized trial of interferon beta-1a in chronic inflammatory demyelinating polyradiculoneuropathy, NEUROLOGY 1999, Vol 58. pages 57-61, see entire document.	1-36
X	VAN DER MEIDE. P. H. Discontinuation of treatment with IFN-beta leads to exacerbation of experimental autoimmune encephalomyelitis in Lewis rats. Rapid reversal of the antiproliferative activity of IFN-beta and excessive expansion of autoreactive T cells as disease promoting mechanisms, Journal of Neuroimmunology, 1998, Vol 84 pages 14-23, see entire document.	1-36
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents:		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"B"	earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	
Date of the actual completion of the international search 25 October 2005 (25.10.2005)		Date of mailing of the international search report 28 NOV 2005
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner of Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer Jegatheesan Seharaseyon <i>Janeie Ford</i> Telephone No. 703-308-0196 <i>for</i>

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/30532

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-36

Remark on Protest

☐

The additional search fees were accompanied by the applicant's protest.

☐

No protest accompanied the payment of additional search fees.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-36, drawn to the special technical feature of a use of interferon beta (IFN-beta) in the manufacture of a medicament for the treatment of chronic demyelinating motor neuropathy.

Group II, claim(s) 37-65, drawn to the special technical feature of a method of treating demyelinating motor neuropathy, comprising administering to the mammal a therapeutically effective amount of an IFN-beta.

Group III, claim(s) 66-67, drawn to the special technical feature of a method of treating CIDP, comprising administering to the subject having CIDP a pharmaceutically effective amount of an IFN-beta and further administering to the subject an immunosuppressant or subjecting the subject to plasmapheresis.

Group IV, claim(s) 68-71, drawn to the special technical feature of a method of treating CIDP, comprising administering to the subject having CIDP a pharmaceutically effective amount of an IFN-beta therapeutic in combination with a second CIDP treatment, wherein administration of the IFN-beta therapeutic is via a non-subcutaneous parental route.

Group V, claim(s) 72-80, drawn to the special technical feature of a method of treating CIDP in a subject receiving a first CIDP treatment selected from the group consisting of administration of a steroid; administration of an anti-inflammatory drug; administration of IVIG and plasmapheresis, in addition to the first CIDP treatment a dose of IFN-beta in an amount to provide effective relief from symptoms of CIDP.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claims 1-36 at least are anticipated by Haden et al. or van der Meide et al. Consequently, the special technical feature which links Group I to Group II-V, does not provide a contribution over the prior art, so unity of invention is lacking.

Invention I is directed to a use and invention II-V are directed to methods that do not share the method steps and have divergent goals. Inventions II-VI are distinguished, from each other as they are directed to non-equivalent methods. Invention I is a use of interferon beta (IFN-beta) in the manufacture of a medicament for the treatment of a chronic demyelinating motor neuropathy. Invention II is a method for treating demyelinating motor neuropathy, comprising administering to the mammal a therapeutically effective amount of an IFN-beta. Invention III is a method for treating CIDP, comprising administering to the subject having CIDP a pharmaceutically effective amount of an IFN-beta and further administering to the subject an immunosuppressant or subjecting the subject to plasmapheresis. Invention IV is a method for treating CIDP, comprising administering to the subject having CIDP a pharmaceutically effective amount of an IFN-beta therapeutic in combination with a second CIDP treatment, wherein administration of the IFN-beta therapeutic is via a non-subcutaneous parental route. Invention V is a method for treating CIDP in a subject receiving a first CIDP treatment selected from the group consisting of administration of a steroid; administration of an anti-inflammatory drug; administration of IVIG and plasmapheresis, in addition to the first CIDP treatment a dose of IFN-beta in an amount to provide effective relief from symptoms of CIDP.

The claims of these groups are directed to inventions, which are not linked to form a single general inventive concept under PCT Rule 13.1. The claims in groups (I-V) lack the same or corresponding special technical features. In particular, each group is directed to distinguishable methods. Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper.

INTERNATIONAL SEARCH REPORT

PCT/US03/30532

Continuation of B. FIELDS SEARCHED Item 3:
STN search of CAPLUS and USPATFUL
search terms: IFN-beta, demyelinating